

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-752V

(not to be published)

Special Master Corcoran

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PETER C. HARRINGTON,

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Petitioner,

*

Filed: January 19, 2018

v.

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Entitlement; Ruling on Record;

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Influenza (“flu”) Vaccine;

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SECRETARY OF HEALTH

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Guillain-Barré Syndrome (“GBS”).

AND HUMAN SERVICES,

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*

Respondent.

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Jeffrey C. Adams, Largo, FL, for Petitioner.

Amy Kokot, U.S. Dep’t of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT¹

On July 17, 2015, Peter Harrington filed a petition seeking compensation under the National Vaccine Injury Compensation Program (“Vaccine Program”).² In it, Mr. Harrington alleged that the influenza (“flu”) vaccine he received on October 24, 2014, caused him to develop Guillain-Barré syndrome (“GBS”). Petition (ECF No. 1) at 1.

Respondent’s Rule 4(c) Report (filed June 10, 2016 (ECF No. 15)) proposed that in fact Petitioner had *not* experienced GBS. *See* Section 11(c)(1)(D). The parties subsequently filed dueling expert reports, and after my review of them, I determined that this case was best resolved on the papers rather than by hearing. To that end, Petitioner filed a brief in support of his claim, dated July 20, 2017 (ECF No. 24) (“Mem.”), and Respondent thereafter opposed Petitioner’s

¹ Although this Decision has been formally designated “not to be published,” it will nevertheless be posted on the Court of Federal Claims’s website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012)). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision’s inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public. *Id.*

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter “Vaccine Act” or “the Act”]. Individual section references hereafter will be to § 300aa of the Act.

entitlement to a damages award by brief dated August 31, 2017 (ECF No. 25) (“Opp.”). Having completed my review of the evidentiary record and the parties’ filings, I hereby **DENY** Petitioner’s request for compensation, for the reasons stated below.

I. Factual Background

A. Medical Records

On October 24, 2014, Mr. Harrington received the flu vaccine at Graf Clinic in Pensacola, Florida. Ex. 3 at 20. At the time of the vaccination, Petitioner had a history of hypertension, allergies, abdominal pain and obesity. Ex. 2 at 8, 11-17. Earlier records also indicate treatment for a swollen toe, an ear infection, lightheadedness, body aches, congestion, eye twitching, dizziness, and a rash. Ex. 2 at 8-10, 16. In addition, the immediate week before (on October 17, 2014), Petitioner had been treated for a sore throat, nasal congestion, arthralgias, myalgias, and headaches. *Id.* at 18. He was ultimately diagnosed with an upper respiratory infection (“URI”) and proscribed antibiotics. *Id.* As of the October 17th visit, Petitioner’s medications also included Lisinopril, Bentyl, Claritin, and a multivitamin. *Id.* at 18.

Two weeks after the vaccination, on November 6, 2014, Petitioner presented to the emergency room at West Florida Regional Medical Center with complaints of heaviness, shortness of breath, and muscle weakness in his arms and legs, although his physical exam indicated that he had no respiratory distress and his breathing appeared normal. Ex. 4 at 23-24, 26. A neurological examination was conducted, including a tomography of the brain, which revealed no evidence of acute intracranial abnormalities. *Id.* at 24, 27, 33. A chest x-ray was also conducted, displaying no radiographic evidence of an acute disease. *Id.* at 27, 34. Petitioner declined admission to the hospital, but was examined and ultimately diagnosed with anxiety, dysrhythmia, dehydration, anemia, and an electrolyte imbalance. *Id.* at 28.

Petitioner returned to West Florida Hospital on November 10, 2014, now complaining of persistent muscle weakness, discoordination of the hands, and dysphagia, and was admitted. Ex. 5 at 36, 38-40; Ex. 7 at 95-96. Intake notes suggest that Mr. Harrington’s primary care physician requested that he be evaluated for GBS. *Id.* at 41. During this hospital stay, Petitioner was evaluated by Dr. Marcus Schmitz, a neurologist. Ex. 5 at 56. It was during this visit that Petitioner informed Dr. Schmitz that following the flu vaccine he began experiencing adverse symptoms, including paresthesia and numbness in his fingers, legs, and toes which eventually progressed to his chest and arms, and developed a sensation of breathing difficulty. *Id.* at 56. Petitioner also informed Dr. Schmitz that he believed he might have been exposed to a tick. *Id.* After an initial evaluation, Dr. Schmitz allowed for the possibility that Mr. Harrington’s symptoms were consistent with possible acute inflammatory polyneuropathy, or acute autoimmune neuropathy, and that these symptoms could be related to the flu vaccine, but expressed skepticism that Petitioner actually had GBS. *Id.* at 56-57. A physical exam conducted earlier that day also indicated that Mr. Harrington’s reflexes were “brisk and symmetric” and his coordination was normal. *Id.* at 54.

While at West Florida Hospital, Mr. Harrington underwent several diagnostic tests. A lumbar puncture was performed which showed slightly elevated protein levels in his cerebral spinal fluid (“CSF”), but otherwise displayed normal functions and a normal white blood cell count. Ex. 5 at 39, 59. The lumbar puncture did indicate gram-positive cocci³ in his CSF, but the treating physician attributed this to contamination of the equipment used to perform the procedure rather than to an underlying bacterial infection. *Id.* at 60. An MRI of Petitioner’s spinal cord was also conducted that revealed “questionable stenosis,” but otherwise normal imaging, and the treating neurologist did not propose a neurological problem as the source of Petitioner’s symptoms. *Id.* at 39, 59, 77. Petitioner also received an MRI of his brain, which similarly resulted in normal imaging, and contained no evidence of demyelination. *Id.* at 76.

Petitioner was treated with steroids and discharged on November 14, 2014. The discharging physician, Dr. Tanner Eiden, opined that Mr. Harrington likely had a post-viral syndrome, possibly related to a viral URI or the flu vaccine he had received. Ex. 5 at 39. Petitioner’s primary care physician, Dr. Roger Henson, also examined Petitioner during this hospital stay. Ex. 7 at 95-96. After reviewing the admitting physician’s emergency room notes, Dr. Henson’s assessment included muscle weakness, dyspnea, tachycardia, and diarrhea. *Id.* at 96.

Petitioner initially felt better after leaving the hospital, but then returned for a second hospital visit on November 18, 2014, with complaints of malaise, fever, weakness, and fatigue. Ex. 6 at 87. During this visit, Petitioner was seen by Jeffrey Chandler, a nurse practitioner, who reviewed the records and testing completed during Mr. Harrington’s hospital visit the week before, and also examined him. *Id.* at 92. Nurse Chandler did not find any concerning problems, and proposed that Petitioner should follow up with his primary care physician and treating neurologist. *Id.* Supervising physician Dr. Mark Brodeur reviewed Mr. Chandler’s findings and also noted no concerning problems. *Id.*

The next day, on November 19, 2014, Mr. Harrington was seen by another neurologist, Dr. Henry Porter, for a post-hospitalization evaluation. Ex. 8 at 112. Dr. Porter noted that Petitioner reported experiencing weakness and difficulty moving his arms and legs, and difficulty breathing as well. *Id.* Dr. Porter reviewed all relevant testing conducted during Petitioner’s hospital stay, including the brain and spinal MRIs, both of which he noted indicated normal imaging. *Id.* Although Dr. Porter’s assessment included GBS as a possible diagnosis, his notes reiterated that “[Petitioner’s] physical examinations [were] not consistent with Guillain-Barre.” *Id.* at 114. Petitioner returned to see Dr. Henson on November 21, 2014, complaining of worsening episodes of weakness, tingling in his lower legs, fatigue, chills, palpitations, and trouble swallowing. Ex. 7 at 97. Dr. Henson diagnosed Petitioner with muscle weakness, dyspnea, shortness of breath, and

³ Gram-positive cocci is a term used to indicate the presence of bacterial cells in the CSF. *Dorland’s Illustrated Medical Dictionary* 387-79, 801 (32nd ed. 2012). The presence of bacteria in a lumbar puncture can indicate a serious bacterial infection, such as meningitis or encephalitis. *Lumbar Puncture (Spinal Tap): Why It’s Done*, Mayo Clinic, <https://www.mayoclinic.org/tests-procedures/lumbar-puncture/basics/why-its-done/prc-20012679> (last visited Jan. 14, 2018).

tachycardia. *Id.* at 98. Thereafter, Petitioner again presented to Dr. Porter, who diagnosed him with anemia and a vitamin B12 deficiency. Ex. 8 at 116. Dr. Porter recommended that Petitioner began receiving B12 injections to treat these conditions. *Id.*

Not long thereafter, on December 12, 2014, Mr. Harrington saw a third neurologist, Dr. David Bear, with complaints of diffuse weakness, heaviness, difficulty breathing and loss of dexterity in the hands. Ex. 8 at 118. After examining Petitioner, Dr. Bear noted that all of Petitioner's nerve conduction studies produced results within normal limits, and that all examined muscles showed no evidence of electrical instability. *Id.* Dr. Bear reiterated to Petitioner that his tests suggested no evidence of any lumbosacral radiculopathy, plexopathy, myopathy, or diffuse peripheral polyneuropathy. *Id.* Dr. Bear's office notes do not mention a diagnosis.

Thus, less than two months after receiving the flu vaccine, *none* of Mr. Harrington's treaters had concluded that he was experiencing GBS. Even if some had initially proposed it might explain his symptoms, the testing he had received, coupled with medical examinations, had not corroborated that diagnosis.

On January 14, 2015, Petitioner returned to Dr. Porter for a follow-up appointment for his complaints associated with muscle weakness. Ex. 8 at 122. After examination, Dr. Porter determined that Petitioner's symptoms had "completely resolved," and noted that Petitioner seemed to be doing well. Laboratory results obtained during the visit indicated low B12 levels, for which Petitioner was being treated with injections. *Id.* at 122. Dr. Porter's ultimate assessment concluded that Petitioner was recovering from "weakness" dating back to October 2014. *Id.*

The next record filed in this case is dated March 5, 2015, and primarily reflects Petitioner's follow-up appointment with Dr. Henson for ongoing anemia, continued B12 deficiency, hypertension and a rash. Ex. 7 at 101. Laboratory tests completed during this visit indicated Petitioner's continued low levels of B12. *Id.* Approximately six months later, on September 9, 2015, Petitioner had a follow-up appointment with Dr. Henson. *Id.* at 103. During this visit, Petitioner complained of severe fatigue, paresthesia, and tingling in in his extremities. *Id.* Dr. Henson's impressions included hypertension, B12 deficiency, fatigue, malaise, paresthesia, and numbness. *Id.* at 104. None of these records state that Petitioner ever experienced or had been diagnosed with GBS, or that the flu vaccine he received the previous October was connected with any of his symptoms.

Petitioner has also filed records in this action from 2016 visits to Drs. Henson and Porter. *See generally* Ex. 10 at 132-33; 138-41, 152. At these visits, Mr. Harrington again expressed concerns about a variety of symptoms similar to what he complained of after his October 2014 vaccination, but no treaters proposed either that the symptoms were reflective of GBS or that the flu vaccine had any connection to them.

B. *Petitioner's Statement Concerning Treatment History*

In addition to the medical records discussed above, Petitioner offered a statement, dated October 14, 2015, detailing the course of his treatment and health history following his receipt of the flu vaccine. *See* Ex. 1 at 1-7. Mr. Harrington therein asserts that his neurologists did not treat him for GBS because his symptoms were not consistent with a typical GBS patient, and his test results were not definitive. *Id.* at 2. Petitioner maintains that during his treatment, “[he] felt like no one wanted to label [him] with GBS, as if they were trying to avoid having to report it to the CDC.” *Id.* He also states that he continues to experience symptoms, including fatigue, jaw weakness, tingling in his legs, body aches, difficulty in concentration, and mood changes. *Id.* at 3. Although Petitioner routinely experiences these symptoms, he maintains in his health statement that his tests continue to yield normal results. *Id.*

II. Expert Reports

A. *Petitioner’s Expert—Dr. William Shackelford*

Dr. Shackelford submitted two written reports in this case. *See* Expert Report, dated November 26, 2016, filed as Ex. 11 (ECF No. 17-1) (“Shackelford First Rep.”); Expert Report, dated April 10, 2016, filed as Ex. 13 (ECF No. 23) (“Shackelford Second Rep.”). According to Dr. Shackelford, Petitioner experienced GBS following receipt of the flu vaccine.

Dr. Shackelford graduated from the University of Illinois Medical School in 1955, and entered practice in 1956 in Cerro Cordo, Illinois. Shackelford First Rep. at 154⁴; Shackelford Second Rep. at 162. His report indicated that he has remained in that practice until the present time. Shackelford First Rep. at 154. Dr. Shackelford stated that he has administered several thousand flu vaccinations during his years of practice, and has treated “many” patients with GBS. *Id.* He considers himself an expert on flu vaccine reactions based on his own experience. *Id.*; Shackelford Second Rep. at 163. Dr. Shackelford’s report did not provide any other details with regard to his qualifications, however, and Petitioner never submitted a CV setting forth Dr. Shackelford’s academic or professional background.

Dr. Shackelford began his analysis by recounting Mr. Harrington’s medical history relating to the flu vaccination and alleged GBS diagnosis. Shackelford First Rep. at 155-57. Although no treating physician ever formally diagnosed Petitioner with GBS, Dr. Shackelford maintained that Petitioner did in fact have a “typical Guillain-Barré reaction.” *Id.* at 158. Dr. Shackelford noted that Petitioner had remained generally healthy prior to receiving the flu vaccine (apart from his past diagnoses of hypertension, allergic rhinitis, and ear infections), but began exhibiting symptoms “a few days later.” *Id.* Furthermore, Dr. Shackelford contended, all of Petitioner’s symptoms were consistent with GBS. *Id.* Overall, Dr. Shackelford’s first report concluded that Petitioner’s GBS injury was caused by the flu vaccine, a determination bulwarked by the fact that treaters could find

⁴Petitioner filed exhibits along with his expert report from Dr. Shackelford (including multiple medical records and his personal health log), totaling 161 pages. *See* Exhibit Expert and Medical Opinion, dated Nov. 29, 2017 (ECF No. 17-1). Although the total page count is 161 pages, Dr. Shackelford’s report (filed separately as Ex. 11) spans only pages 153-159.

“no other cause” for the complained of symptoms. *Id.* at 159.

Dr. Shackelford submitted no medical evidence or scientific literature in support of the statements contained in this first report. The report was also very difficult to follow, as it amounted to a compilation of exhibits from the filed medical record, along with photocopies of handwritten pages on Dr. Shackelford’s stationary setting forth his opinion. *See e.g.*, Ex. 11 at 158.

Dr. Shackelford’s supplemental expert report provided no additional analysis or scientific evidence, but simply repeated the assertions made in his initial report. *See generally* Shackelford Second Rep. In particular, the second report mirrored the first in recounting Petitioner’s medical history and the facts relied on by Dr. Shackelford in opining that the flu vaccine caused Petitioner’s symptoms. *Id.* at 165-67. Overall, Dr. Shackelford maintained again that the flu vaccine caused Petitioner to suffer GBS symptoms “within days” following receipt of the vaccine, and treaters could find no other cause for Petitioner’s symptoms. *Id.* at 168. Again, Dr. Shackelford provided no medical or scientific evidence in support of his assertions, and the second report was characterized by the same handwritten, conclusory statements found in the first. Rather, his final, unsupported analysis summarily concluded that “it is logical to assume the cause and effect between [Petitioner’s] injury and the vaccine.” *Id.*

B. *Respondent’s Expert—Dr. Jeffrey Cohen*

Respondent’s expert filed one written report in this case. *See* Expert Report, dated February 28, 2017, filed as Ex. A (ECF No. 20-1) (“Cohen Rep.”). According to Dr. Cohen, Mr. Harrington’s symptoms were not consistent with GBS, and no treater otherwise definitively diagnosed him with GBS.

Dr. Cohen received his medical degree from the University of Oklahoma College of Medicine, and he completed two fellowships during his postdoctoral training: one in clinical neurology at Massachusetts General Hospital, and one in peripheral nerve diseases at the Mayo Clinic. Cohen CV at 1; Cohen Rep. at 1. He is currently a professor of neurology at Dartmouth Hitchcock Medical Center and the Geisel School of Medicine. Cohen Rep. at 1. He is board certified in neurology, with added qualifications in clinic neurophysiology and neuromuscular disease. *Id.* Dr. Cohen’s primary area of practice involves neuromuscular diseases, including GBS and Chronic Inflammatory Demyelinating Polyradiculoneuropathy. *Id.* He also trains and supervises neurology residents and fellows. *Id.*

According to Dr. Cohen, Petitioner’s symptoms following his receipt of the flu vaccine were inconsistent with GBS. Dr. Cohen based his assertion on a review of the established criteria for a GBS diagnosis. Cohen Rep. at 2; *see also* C. Fokke, et al., *Diagnosis of Guillain-Barré Syndrome and Validation of Brighton Criteria*, 137 *Brain* 33, 33-43 (2014), filed as Ex. C (ECF No. 20-3) (“Fokke”). Fokke was a cohort study examining electrophysiological and laboratory features of adult GBS patients and developed a new set of criteria for a GBS diagnosis, establishing levels of diagnostic certainty based on ranges from one to four, one being the highest and four being the

lowest. Fokke at 34. Criteria for a GBS diagnosis include: bilateral flaccid weakness in the limbs; decreased or absent deep tendon reflexes in the weak limbs; monophasic downward course of symptoms occurring between twelve hours and twenty-eight days post-onset; low CSF protein levels; nerve conduction studies consistent with GBS subtypes; and absence of an alternative diagnosis for the weakness. *Id.* at 38; Cohen Rep. at 2.

Relying on the Fokke criteria, Dr. Cohen opined that Petitioner's clinical course, medical evaluations, and testing results did not suggest that he suffered from GBS. Cohen Rep. at 3 (Petitioner's "clinical course, normal neurological examinations, spontaneous improvements despite no therapy, his CSF picture, and normal NCV's make [a GBS] diagnosis untenable"). Mr. Harrington never displayed bilateral flaccid paralysis in his limbs, but only complained of weakness, and numerous evaluations documented his normal strength. Cohen Rep. at 2. In addition, Petitioner's treating neurologists never noted any decreased or absent tendon reflexes in the weakened limbs. *Id.* Finally, Petitioner's symptoms tended to get better over time and then worsen, rather than spiral downward in the progressive, acute manner consistent with the expected GBS nadir. *Id.* Petitioner's symptoms could just as credibly be attributed to his documented anxiety with hyperventilation, evidenced by symptoms including a racing heart, difficulty breathing, jaw symptoms, and twitching, all of which were symptom's Petitioner experienced. *Id.*; *see also* J. Stone, et al., *The Symptom of Functional Weakness: A Controlled Study of 107 Patients*, 133 *Brain* 1537, 1537-38, 1540-41, 1549 (2010), filed as Ex. E (ECF No. 20-5).

Dr. Cohen also discussed some of the specific test results that initial treaters seemed to have taken into account in first including GBS in the differential diagnosis. He opined that Petitioner's elevated CSF protein levels were most likely due to a grossly, bloody spinal tap. Cohen Rep. at 2. According to Dr. Cohen, a traumatic spinal tap could lead to elevated protein levels. *Id.*; *see also* D. Seehusen et al., *Cerebrospinal Fluid Analysis*, 68 *Am. Family Physician* 1103, 1106 (2003), filed as Ex. D (ECF No. 20-4). By contrast, Petitioner's nerve conduction studies yielded normal results in his lower extremities. *Id.* at 3.

Besides rejecting the GBS diagnosis given the medical record, Dr. Cohen dismissed Dr. Shackelford's assertions as conclusory, noting that his notes only suggested a GBS reaction, with no theory or evidence to support the assertions. *Id.* at 3. Dr. Cohen maintained that Dr. Shackelford's opinions were "not based on any clear reasoning" and ultimately gave no explanation of Petitioner's symptoms beyond his statement that Petitioner suffered from a "typical GBS reaction." *Id.*

III. Procedural History

Petitioner initiated this case on July 17, 2015. Pet. at 1. After obtaining and filing medical records from July 2015 to February 2016, Respondent filed a Rule 4(c) Report on June 10, 2016, setting forth the view that Petitioner was not entitled to compensation because he had failed to establish a GBS diagnosis. ECF No. 15. Petitioner then filed his first expert report from Dr. Shackelford on November 29, 2016, after receiving two extensions of time to act. ECF No. 17. Thereafter, Respondent filed his expert report from Dr. Cohen on February 28, 2017. ECF No. 20.

After the filing of the initial expert reports, I held a status conference on March 7, 2017, to discuss what I perceived as weaknesses in Petitioner's claim. In particular, I expressed my concerns that (as pointed out by Dr. Cohen's report) Petitioner's medical records did not support a GBS diagnosis. *See* Order, dated Mar. 7, 2017 (ECF No. 21). In addition, I informed Petitioner that Dr. Shackelford's report was unpersuasive and deficient, although I nevertheless provided Petitioner the opportunity to supplement it. *Id.* at 1. In response, Petitioner submitted another expert report from Dr. Shackelford, which (as noted above) largely mirrored the first report filed, addressing none of my concerns. ECF No. 23.

I subsequently held another status conference, at which time I proposed ruling on the record in this matter in lieu of a hearing. The parties did not object to my proposal. Petitioner filed a brief in support of his claim on July 20, 2017, and Respondent filed her brief in opposition on August 31, 2017. The matter is ripe for adjudication.

IV. Parties' Respective Arguments

Petitioner's submission attempts to remedy his lack of supporting medical record and scientific evidence bulwarking the assertion that he suffered from GBS as a result of the flu vaccine. In support of his Table claim⁵, Petitioner maintains that a formal GBS diagnosis is not required, as long as he can establish "a timely connection with the inoculation and direct harm to the patient" Mem. at 8 (citing 42 C.F.R. § 100.3(a)). Petitioner acknowledges that his medical records do not support a GBS diagnosis, but maintains that they did demonstrate a timely connection and a direct harm. *Id.* Regarding his non-table claim, Petitioner analyzes the prongs of the test set forth by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005), arguing that he satisfies all three. Mem. at 8-9. More specifically, Petitioner argues that Dr. Shackelford's causation opinion that there is no alternate explanation for Petitioner's symptoms is enough to satisfy *Althen* Prongs One and Two. *Id.* And a three-day symptom onset (also unsupported) is a medically appropriate timeframe to warrant entitlement to compensation under the third prong. *Id.*

Respondent's opposition brief stresses that the medical records do not support Petitioner's assertion that he suffered from GBS. Opp. at 10. Petitioner was never conclusively diagnosed with GBS, and in fact some treaters explicitly stated that his symptoms were inconsistent with such a diagnosis. *Id.* Respondent also dismisses Dr. Shackelford's opinion as unreliable, noting that he submitted no scientific evidence in support of his opinions. *Id.* at 11. Thus, Petitioner has not satisfied any of the *Althen* prongs, because Petitioner's expert sets forth no reliable, supported

⁵ Although the Petition in this case was filed in July 2015 – and hence *before* the Vaccine Table was amended as of February 2017 to include GBS as a flu vaccine-caused injury – and although it does for formally state a Table claim, Petitioner has argued as if his claim nevertheless could meet the standards for such a claim. *See, e.g.*, Mem. at 6 (ECF No. 24). For purposes of allowing Petitioner every opportunity to make his case, I have analyzed his arguments about the sufficiency of his Table claim as if the claim itself had been filed after the amendment.

causation theory and no medically supported onset timeframe. *Id.* at 12. Petitioner has therefore failed to support his alleged vaccine injury and is not entitled to compensation. *Id.* at 13.

V. Relevant Legal Standards

A. Claimant's Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a “Table Injury” – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).

For both Table and Non-Table claims, Vaccine Program petitioners bear a “preponderance of the evidence” burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was “not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury.” *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a “reputable medical theory,” demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, the petitioner’s theory must be based on a “sound and reliable medical or scientific explanation.”

Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be “legally probable, not medically or scientifically certain.” *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed “not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act’s preponderant evidence standard.” *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec’y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) (“[p]lausibility . . . in many cases may be enough to satisfy *Althen* prong one” (emphasis in original)). But this does not negate or reduce a petitioner’s ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner’s medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine “did cause” injury, the opinions and views of the injured party’s treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 (“medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a ‘logical sequence of cause and effect show[s] that the vaccination was the reason for the injury’”) (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec’y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician’s views do not per se bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that “[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court”); *Snyder v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) (“there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted”). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions

among such individuals. *Hibbard v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians’ conclusions against each other), *aff’d*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff’d*, 463 F. App’x 932 (Fed. Cir. 2012); *Veryzer v. Sec’y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den’d*, 100 Fed. Cl. 344, 356 (2011), *aff’d without opinion*, 475 Fed. App’x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a “proximate temporal relationship” between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase “medically-acceptable temporal relationship.” *Id.* A petitioner must offer “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one’s requirement). *Id.* at 1352; *Shapiro v. Sec’y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den’d after remand*, 105 Fed. Cl. 353 (2012), *aff’d mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec’y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den’d* (Fed. Cl. Dec. 3, 2013), *aff’d*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider “all [] relevant medical and scientific evidence contained in the record,” including “any diagnosis, conclusion, medical judgment, or autopsy or coroner’s report which is contained in the record regarding the nature, causation, and aggravation of the petitioner’s illness, disability, injury, condition, or death,” as well as “the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.” Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec’y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master’s discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and “complete” (i.e., presenting all relevant information on a patient’s health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec’y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) (“[g]iven the inconsistencies between petitioner’s testimony and his

contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human*

Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records over contrary testimony, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the weighing of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g., Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's

case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the ipse dixit of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

D. *Consideration of Medical Literature*

Respondent's expert filed some medical and scientific literature in this case, including articles offered in support of their causation theories. *See generally* Exs. 21 and 24–30. I have reviewed all of the medical literature submitted in this case, although my decision does not discuss each filed article in detail. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted). This is due to the fact (as expanded upon below) that the theories for which they are offered have been addressed at length in prior decisions—but in no cases have petitioners previously succeeded in meeting their burden of proof with respect to such theories.

E. *Resolution of Case Via Ruling on Record*

After a status conference held on June 19, 2017, I proposed determining entitlement based on written submissions and evidentiary filings, including both side's expert reports, rather than by holding a hearing, and the parties acceded to my proposal. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

After careful review of the expert reports, medical records, and the arguments of both sides, and taking into account my own experience resolving similar claims (as well as parallel decisions from other Vaccine Act cases), I conclude that Petitioner has not established preponderant evidence in favor of his claim.

I. Petitioner Has Not Established GBS as His Injury

The record evidence does not support Petitioner's principal allegation: that he suffered from GBS after his October 2014 vaccination. Vaccine claimants must establish evidence of an injury in order to prevail. *See Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (a petitioner "must specify his vaccine-related injury and shoulder[s] the burden of proof of causation"). Here, there is no evidence in the record that any treater diagnosed vaccine-induced GBS at or around the time of the vaccination, or later for that matter. At best, the record suggests that certain treaters initially considered GBS as a possible explanation for Petitioner's symptoms, but later abandoned it after test results came in that did not corroborate the diagnosis. While contemporaneous records do indicate that Petitioner was experiencing adverse symptoms in the time after his vaccination, no treaters definitely related those symptoms to GBS. Dr. Cohen's report also persuasively explained why Petitioner's symptoms and test results did not satisfy the current clinical criteria for a GBS diagnosis.

Petitioner cites to medical records (in particular Ex. 7 at 56-59, 76-77, 118; Ex. 8 at 112-114) in which treaters referred to possible GBS or symptoms of unknown origin, or instances where treaters proposed a possible link between the flu vaccine to Petitioner's symptoms. But this evidence has far less probative value than Petitioner assumes. The fact that treaters reasonably allowed for the possibility of a GBS diagnosis based on initial, limited information must be considered against the entire record. And, as that record reveals, most of Petitioner's treaters later stated either that they had no explanation for Petitioner's symptoms, or that they did not believe his symptoms were related to GBS after taking into account additional relevant testing (for example, reflex tests or nerve conduction studies). Thus, looking at the entirety of the record rather than just portions of it, preponderant evidence does not support the conclusion that Mr. Harrington "more likely than not" experienced GBS. This leaves only Petitioner's own statements that he suffered from vaccine-induced GBS, which are by themselves insufficient evidence to base factual determination supportive of a finding of entitlement. *See* Section 13(a)(1); *see, e.g., Lozano v. Sec'y of Health & Human Servs.*, No. 15-369V, 2017 WL 3811124, at *7 (Fed. Cl. Spec. Mstr. Aug. 4, 2017).

II. Petitioner's Table Claim is Not Supported by Preponderant Evidence

Petitioner's Table injury claim is based on the allegation that he experienced GBS after receiving the flu vaccine. Pet. at 1. However, the evidence offered by Petitioner establishing his post-vaccination symptoms does not satisfy the Table definition for GBS as set forth in the Vaccine

Table. The Vaccine Injury Table requires a petitioner alleging this kind of claim to establish onset of GBS within three to forty-two days post-vaccination (42 C.F.R. § 100.3(a)(XIV)(D)), and that in fact he suffered from GBS. In the present case, however, Petitioner was never affirmatively diagnosed with GBS, regardless of when his symptoms began. Furthermore, Petitioner's treating physicians indicated that his symptoms were *not* related to GBS, despite some initial suspicions. Overall, Petitioner did not offer any compelling testimony or other evidence to refute the contemporaneous medical records. Thus, Petitioner has not shown it to be more likely than not that he was in fact suffering from GBS, and that his medical records were somehow incorrect.

III. Petitioner has not satisfied the Three *Althen* Prongs

Apart from the fact that Petitioner has not shown that he was in fact diagnosed with GBS, Petitioner has failed to offer a reliable, persuasive medical or scientific theory supporting a causal connection between the vaccine and his alleged injury. Dr. Shackelford's opinion was unpersuasive, conclusory, and disjointed, and was also unsupported by any corroborative literature that might have made up for its facial deficiencies.⁶ Dr. Cohen, by contrast, credibly rebutted Petitioner's allegations, noting that Petitioner had not satisfied the GBS diagnostic criteria. Thus, Petitioner cannot satisfy *Althen* prong one. I acknowledge that, given the large number of Program cases in which the flu vaccine has been found to be causal of GBS, had Petitioner's injury been properly characterized as GBS, my resolution of this component of his case would be different, in spite of the deficiencies in Dr. Shackelford's opinion. As it is, however, Mr. Harrington has not successfully demonstrated that the symptoms he experienced post-vaccination, whatever they were, could have been caused by the flu vaccine.

Petitioner's obligation under the second *Althen* prong was to demonstrate a logical sequence of cause and effect connecting the particular facts of her case to a medical theory. *See, e.g., Sturdivant v. Sec'y of Health & Human Servs.*, No. 07-788V, 2016 WL 552529, at *18 (Fed. Cl. Spec. Mstr. Jan. 21, 2016) (prong two requires a fact-based inquiry into whether the vaccine in question *did* cause the particular injury). But again, Petitioner's expert offered no persuasive, reliable explanation for how the facts contained in the medical record establish that the flu vaccine caused Mr. Harrington's injuries, and he failed to provide a cogent, understandable opinion setting forth a logical sequence of cause and effect. Instead, Dr. Shackelford simply assumed a causal relation based on a purported lack of alternate explanation for Petitioner's symptoms⁷, and offered

⁶ As previously noted, Vaccine Act claimants are not *required* to offer medical or scientific literature to prevail. *Andreu*, 569 F.3d at 1378-79. But where a claimant's expert report is facially thin or conclusory – as is the case here – and where medical or scientific literature could help bulwark the report's facial deficiencies, it is reasonable to take into account the absence of such supportive evidence when evaluating the sufficiency of the claimant's first prong showing under *Althen*.

⁷ In fact, there are multiple alternative diagnoses noted in Petitioner's medical records, any of which could be the cause of his symptoms. For example, the records indicate that Petitioner was diagnosed with a URI a week prior to receiving the flu vaccine. Ex. 2 at 18. Earlier records indicate treatment for hypertension, body aches, dizziness, and abdominal pain. *Id.* at 8-10, 16. Records post-vaccination also show that Petitioner was diagnosed with anxiety, dysthymia, anemia, muscle weakness, tachycardia, and a B12 deficiency. Ex. 4 at 28; Ex. 5 at 96; Ex. 8 at 16.

no explanatory support for his opinion.

The third *Althen* prong would have evidentiary support if Petitioner had been able to demonstrate that he suffered from GBS, given that his symptoms began within two to three weeks of the flu vaccine's administration – a timeframe well within what is considered medically acceptable for the onset of GBS after receipt of the flu vaccine. *See Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557, at *13 (Fed. Cl. Spec. Mstr. Nov. 12, 2014) (asserting that eight weeks is the longest reasonable timeframe for a flu/GBS claim). But because Dr. Shackelford did not persuasively establish that a non-GBS injury consistent with what Petitioner experienced could be vaccine-caused, he has also failed to demonstrate that the timing of onset of those same symptoms was medically acceptable.

CONCLUSION

The record does not support Mr. Harrington's contention that the flu vaccine caused him to develop GBS, and the expert support offered for his claim was deficient. Petitioner has therefore not established entitlement to a damages award, and I must DISMISS his claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.⁸

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

⁸ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.